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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/765,498      | 01/26/2004  | Mark R. Vandlik      | F-5489 CIP 2 CON    | 2510             |

7590 05/09/2007  
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| EXAMINER |
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DEAK, LESLIE R

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| ART UNIT | PAPER NUMBER |
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3761

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05/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/765,498             | VANDLIK ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Leslie R. Deak         | 3761                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 9-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1/26/04, 12/8/04, 12/13/04, 12/12/05, 8/2/06.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Species A in the reply filed on 2 August 2006 is acknowledged. Claims 9-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2 August 2006.

### ***Interference***

2. Applicant's request for an interference dated 12 December 2005 has been noted. However, applicant has withdrawn the interfering claims from prosecution. As such, the request will be held in abeyance.

### ***Claim Rejections - 35 USC § 101/112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitation "the controller" in line 2. There is insufficient antecedent basis for this limitation in the claim, since none of the parent claims reference a controller. Therefore, the scope of the claim is unclear. For the

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purposes of prosecution on the merits, Examiner has interpreted the claim to recite a controller.

5. Claim 8 provides for the use of the blood processing system set forth in the parent claims, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 4, 5/1, 5/4, 7/1, 7/4, 8/1, and 8/4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,649,903 to Deneiga et al in view of US 5,591,337 to Lynn et al.

In the specification and figures, Deniega discloses the apparatus substantially as claimed by applicant. With regard to claim 1, Deniega discloses a blood processing system that includes a source of blood cells 74, and a flow channel or tube 92 connecting the source 74 that leads to a storage container 88. Between the source 74 and the storage container 88 is a leukocyte reduction filter 60b (see FIG 1, column 5 line 58 to column 6, line 14). The apparatus further comprises pump station P3 that pumps blood from the source 74, through the filter 60b, to the collection container 88 via flow channel 92 (see column 12, lines 22-52).

Deneiga fails to disclose that the leukocyte filter comprises two flexible housings with a fibrous filter medium and seal as claimed by applicant. However, Lynn discloses a fibrous leukocyte filter 16 with a flexible housing that conforms and is compliant to various pressures during use (see column 2, lines 15-22). The filter housing 18 comprises two sheets 44, 46 of flexible material that surround fibrous filter pad assembly 20 (see FIG 6, column 8, lines 58-65, column 10, lines 53-55). The housing further comprises an integrated fluid tight seal 48 that incorporates the housing 44, 46, and filter pad assembly 20, wherein the seal is formed by a one-step application of pressure and radiofrequency heating (see column 9, lines 1-24).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the leukocyte filter with a flexible housing and fluid tight seal as disclosed by Lynn in the blood processing system disclosed by Deneiga in order to provide a compliant filter with a fluid tight seal, as taught by Lynn (see column 2, lines 15-22, column 10, lines 47-49).

With regard to claim 4, Deneiga discloses that the blood processing system comprises a donor flow channel 24 and a blood separation apparatus or centrifuge 44 (see column 4, lines 31-48).

With regard to claim 5/1 and 5/4 as interpreted by the examiner, Deniega discloses that the blood processing system comprises a microprocessor or controller (see column 10, lines 28-32). With regard to applicant's recitation concerning the operation of the controller, such statements are considered by the examiner to be a recitation of the intended use of the controller. It has been held that a recitation with regard to the manner in which a claimed device is intended to be employed does not differentiate over a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the microprocessor controlled system disclosed by Deniega is capable of being programmed to operate as claimed by applicant, thereby meeting the limitations of the claims.

With regard to claims 7/1 and 7/4, applicant recites the use of red blood cells in the source of blood cells. Such statements are considered by the examiner to be a recitation of the intended use of the processing system. It has been held that a recitation with regard to the manner in which a claimed device is intended to be employed does not differentiate over a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant's recitation of the type of cells within the source container fails to structurally distinguish the source of blood cells disclosed in the prior art from the instantly claimed apparatus. The blood processing system disclosed

by Deniega and Lynn is capable of providing red blood cells to the blood source for filtration, meeting the limitations of the claims.

With regard to claims 8/1 and 8/4, applicant fails to set forth any steps in the claimed process. Thus, it is the position of the examiner that the combined device suggested by Deniega and Lynn is capable of processing blood, thereby meeting the limitations of the claims.

8. Claims 2, 3, 5/2, 5/3, 7/2, 7/3, 8/2, and 8/3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,649,903 to Deneiga et al in view of US 5,591,337 to Lynn et al, further in view of US 5,858,015 to Fini.

In the specification and figures, Deneiga and Lynn disclose the device substantially as claimed by applicant (see rejection above) with the exception of a fixture to restrain expansion of the filter housing. Fini discloses a container 1 with a rigid support 7, a flexible membrane or housing 7 that encloses the container, and a filter 9 within the container (see columns 3-4, FIG 1). Rigid support 7 serves to keep the filter in place during use without deformation resulting from the variations in the volume of the container itself (see column 2, lines 10-14). With regard to applicant's recitation concerning the function of the fixture (claim 2), such statements are considered by the examiner to be a statement of the intended use of the device. It has been held that a recitation with regard to the manner in which a claimed device is intended to be employed does not differentiate over a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the rigid support 7 disclosed



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by Fini is capable of restraining lateral expansion of the container 1, meeting the limitations of the claim.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the blood processing system and filter disclosed by Deniega and Lynn with the fixture or support member disclosed by Fini in order to prevent deformation of the filter medium from variations in container or housing volume, as taught by Fini (see column 2, lines 10-14).

With regard to claim 3, Deneiga discloses that the blood processing system comprises a donor flow channel 24 and a blood separation apparatus or centrifuge 44 (see column 4, lines 31-48).

With regard to claim 5/2 and 5/3 as interpreted by the examiner, Deniega discloses that the blood processing system comprises a microprocessor or controller (see column 10, lines 28-32). With regard to applicant's recitation concerning the operation of the controller, such statements are considered by the examiner to be a recitation of the intended use of the controller. It has been held that a recitation with regard to the manner in which a claimed device is intended to be employed does not differentiate over a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the microprocessor controlled system disclosed by Deniega is capable of being programmed to operate as claimed by applicant, thereby meeting the limitations of the claims.

With regard to claims 7/2 and 7/3, applicant recites the use of red blood cells in the source of blood cells. Such statements are considered by the examiner to be a

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recitation of the intended use of the processing system. It has been held that a recitation with regard to the manner in which a claimed device is intended to be employed does not differentiate over a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant's recitation of the type of cells within the source container fails to structurally distinguish the source of blood cells disclosed in the prior art from the instantly claimed apparatus. The blood processing system disclosed by Deniega, Lynn, and Fini is capable of providing red blood cells to the blood source for filtration, meeting the limitations of the claims.

With regard to claims 8/2 and 8/3, applicant fails to set forth any steps in the claimed process. Thus, it is the position of the examiner that the combined device suggested by Deniega, Lynn, and Fini is capable of processing blood, thereby meeting the limitations of the claims.

9. Claims 6/1 and 6/4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,649,903 to Deneiga et al in view of US 5,591,337 to Lynn et al, further in view of US 5,423,738 to Robinson et al.

In the specification and figures, Deniega and Lynn disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of a fluid actuated pump and associated actuator. Robinson discloses a blood separation system that uses pneumatically actuated diaphragm pumps to move blood through the system with accumulators or actuators since the diaphragm pump does minimal damage to blood cells moving through the pump (see column 21, lines 55 through column 22, line 21). Therefore, it would have been obvious to one having ordinary skill in the art at the

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time the invention was made to use fluid actuated pumps and actuators as disclosed by Robinson in the blood processing and filtration system disclosed by Deniega and Lynn in order to prevent damage to the blood cells, as taught by Robinson (see column 22, lines 3-8).

10. Claims 6/2 and 6/3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,649,903 to Deneiga et al in view of US 5,591,337 to Lynn et al, in view of US 5,858,015 to Fini, further in view of US 5,423,738 to Robinson et al.

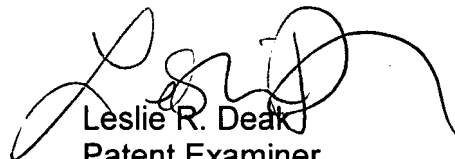
In the specification and figures, Deniega, Lynn, and Fini disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of a fluid actuated pump and associated actuator. Robinson discloses a blood separation system that uses pneumatically actuated diaphragm pumps to move blood through the system with accumulators or actuators since the diaphragm pump does minimal damage to blood cells moving through the pump (see column 21, lines 55 through column 22, line 21). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use fluid actuated pumps and actuators as disclosed by Robinson in the blood processing and filtration system disclosed by Deniega, Lynn, and Fini in order to prevent damage to the blood cells, as taught by Robinson (see column 22, lines 3-8).

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
11 October 2006